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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,527	12/27/2001	Raymond L. Houghton	210121.513C1	7914

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,527	HOUGHTON ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/15/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III, claims 37-46 in the reply filed on August 29, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-36 have been canceled. Claims 37-46 are pending.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed fail to provide adequate support under 35 USC 112 for claims 39, 40, 43, 44, 45 and 46 of this application. The Examiner has reviewed provisional applications:

60/194,241 filed April 3, 2000;

60/219,862, filed July 20, 2000;

60/221,300, filed July 27, 2000; and

60/256,592, filed December 18, 2000.

The sequences elected in instant invention are not of record in the aforementioned provisional applications. Moreover, the composition as claimed in the instant invention is not set forth in the provisional applications. Accordingly, priority of the instant claimed invention is afforded the filing date of December 27, 2001.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 37-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for determining the presence of a breast cancer cell in a patient, said method comprising utilizing specific elected sequences, it does not reasonably provide enablement for a composition for determining any and all cancers using the elected sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants' claims broadly read on a composition for detecting any type of cancer utilizing the methods of polymerase chain reaction (PCR) and immunocapture, which use specific polynucleotide sequences and a specific antibody. It is art known that there are different types of cancer with differing pathologies and etiologic agents, therefore it follows that the diagnosis of one type of cancer will not definitively result in the effective diagnosis or determination of another.

The art supports that GABA (SEQ ID NO: 75; {*Hedblom et al. Journal of Biological Chemistry, vol. 272, no. 24, pages 15346-15350, 1997; IDS AE*}) and B305D isoform (SEQ ID NO: 7;{*Xu et al., US 6329505 B1*) are genes recognized to be over-expressed in breast tumors. However, there is no evidence of record or suggested in the art that the utilization of the elected sequences corresponding to these breast tissue specific genes would be helpful in the diagnosis

of cancers other than breast cancer. While there is a need to identify new targets to establish tumor markers there must be a careful analysis of each candidate target and its correlation to an organ system, expression level and disorder. Applicants' disclosure does not support the implementation of the claimed composition in the definitive determination of any and all cancers or the detection of any and all cancer cells. In the absence of an established role of the oligonucleotides in cancerous diseases other than breast, it is impossible to predict if the claimed method would be effective in diagnosis of any and all cancers or in detecting any and all cancer cells.

Furthermore, the detection of any polynucleotide that hybridizes to any of the oligonucleotides/polynucleotides germane to the composition is not a full proof means of determining the presence or absence of any cancer or cancer cell. Fragments of nucleic acid sequences could hybridize to the polynucleotides set forth in the claims, however this observation could not be extrapolated by one of ordinary skill in the art to mean that the sample is cancerous.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See *In re Fisher*, 166 USPQ 19 24 (CCPA 1970). Based on the analysis and the teachings presented above it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 37, 38, 41, 42 rejected under 35 U.S.C. 102(b) as being anticipated by Harada et al (Proc. Natl. Acad. Sci. USA, vol. 90, pages 11312-11316, December 1993). Regarding claim 37 and 38, Harada et al teach a composition comprising (a) first oligonucleotide and a second oligonucleotide, wherein said first oligonucleotide and said second oligonucleotide hybridizes to a first polynucleotide and to a second polynucleotide respectively; wherein said first polynucleotide is unrelated in nucleotide sequence from said second polynucleotide and wherein said first polynucleotide and said second polynucleotide are tissue specific polynucleotides of the a cancer cell to be detected. Harada et al further teaches wherein said first polynucleotide and said second polynucleotide are complementary tissue-specific polynucleotides of the tissue type of said cancer cell (see entire reference, especially section entitled "Material"; see also section entitled "Discussion").

Regarding claims 41 and 42, Harada et al teach a composition comprising a first oligonucleotide pair and a second oligonucleotide pair; wherein said first oligonucleotide pair and second oligonucleotide pair hybridizes to a first polynucleotide and to a second polynucleotide, wherein said first polynucleotide is unrelated in nucleotide sequence from said second polynucleotide and wherein said first polynucleotide and said second polynucleotide are

tissue-specific polynucleotides of a cancer cell to be detected ((see entire reference, especially section entitled "Material"; see also section entitled "Discussion").

7. Claims 37-38, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Frudakis et al (IDS, AK). Regarding claims 37 and 38, Frudakis et al teach a composition comprising (a) first oligonucleotide and a second oligonucleotide, wherein said first oligonucleotide and said second oligonucleotide hybridizes to a first polynucleotide and to a second polynucleotide respectively; wherein said first polynucleotide is unrelated in nucleotide sequence from said second polynucleotide and wherein said first polynucleotide and said second polynucleotide are tissue specific polynucleotides of the a cancer cell to be detected. Harada et al further teaches wherein said first polynucleotide and said second polynucleotide are complementary tissue-specific polynucleotides of the tissue type of said cancer cell (page 19)

Regarding claims 41 and 42, Frudakis et al teach a composition comprising a first oligonucleotide pair and a second oligonucleotide pair; wherein said first oligonucleotide pair and second oligonucleotide pair hybridizes to a first polynucleotide and to a second polynucleotide, wherein said first polynucleotide is unrelated in nucleotide sequence from said second polynucleotide and wherein said first polynucleotide and said second polynucleotide are tissue-specific polynucleotides of a cancer cell to be detected (page 26).

Prior art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Zehentner et al. (Clinical Chemistry 48(8): 1225-1231, August 2002).

Conclusion

8. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

CYNTHIA WILDER
PATENT EXAMINER
11/9/2005